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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 01/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,773

Applicant(s)

WEINBERGER, JUDAH Z.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-13 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-13 and 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 16 October 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed October 16, 2002. The Examiner acknowledges the amendments to the specification; the amendments to the drawings; the amendments to claims 1, 8, 22, 25 and 28; and the cancellation of claims 5, 14-21, 31 and 32. Claims 1-4, 6-13 and 22-30 are pending.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on October 16, 2002 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Specification

3. The objections to the specification set forth in the Office Action mailed June 11, 2002 have been withdrawn in view of the Amendment filed October 16, 2002.

Claim Objections

4. The objections to the claims set forth in the Office Action mailed June 11, 2002 have been withdrawn in view of the Amendment filed October 16, 2002.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4, 6-13, 22-24, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, it is unclear from the language of the claim in lines 8-9 whether or not the shape of the tube segment is determined by the shape of the balloon. Furthermore, it is unclear what is the shape of the balloon.

Regarding claim 8, it is unclear from the language of the claim in lines 8-9 whether or not the shape of the tube segment is determined by the shape of the balloon. Furthermore, it is unclear what is the shape of the balloon.

Regarding claims 12 and 13, it is indefinite whether or not the claims are accurate. Claim 12 recites that “the tube segment is adhesively attached to the balloon or catheter shaft” and claim 13 recites that “the tube segment is attached to the balloon or catheter shaft by heat sealing.” It is unclear how the tube segment can be attached to the balloon or catheter and still be “longitudinally slid over” the balloon as set forth in independent claim 8.

Regarding claim 22, it is unclear from the claim language what element of the balloon catheter is “slideable over the balloon catheter”; what element of the balloon catheter is “of expandable and collapsible material”; and what element of the balloon catheter “includes radioactive material.”

Regarding claims 29 and 30, the preamble of the claims is inconsistent with that of the corresponding independent claim 28. Claim 28 recites an apparatus. Claims 29 and 30 recite a tube segment. It is unclear whether claims 29 and 30 are further limiting the combination of elements that form the apparatus or merely the tube segment of the apparatus. This rejection was made in the Office Action mailed June 11, 2002. The Remarks in the Amendment filed October 16, 2002 indicate that claims 29 and 30 have been amended to overcome said rejection, but said Amendment includes no formal amendment to the claims. As such, the rejection is maintained.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, 7, 8, 10 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein ('284). Klein teaches device for radiation treatment of an internal body organ. The device includes a balloon catheter 34 having an inflatable balloon 32 and a cylindrical, elastic radioactive tube 10 that is longitudinally slidable over the balloon catheter. The cylindrical radioactive tube includes a distal tube segment 18,42 formed of a mixture of radioactive material 30 and non-radioactive material 38. The tube segment 18,42 can be an expandable and

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collapsible material. The tube segment is expandable in a range of sizes. In operation, the balloon catheter is inserted into the body lumen; the radioactive tube is longitudinally slid over the balloon catheter such that the tube segment is disposed over the balloon; the balloon is inflated with fluid to expand the tube segment and administer a radiation dose to the luminal structure; the balloon is deflated and the tube segment collapsed; and the balloon catheter and tube are removed from the luminal structure.

9. Claims 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Delfino et al. ('658). Delfino et al. teach a cylindrical stent for in vivo implantation. The stent is a tubular segment and includes a radioactive material for producing radiation. The radiation dose can be made to vary along axial and longitudinal dimensions of the tube segment by using varying concentrations of radioactive material (Fig. 7, col. 8, line 27- col. 9, line 5).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Hess ('168). Klein teaches all of the limitations of the claims except that the radioactive material is in the form of a coating on the tube segment. It is well known in the art

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that a non-radioactive material can be provided with radioactive characteristics by coating the non-radioactive material with a radioactive material. Hess teaches a stent 74 which is coated with a radioactive material in order to assist in preventing restenosis of an artery. It would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by coating a tubular segment with a radioactive material in view of the teachings of Hess in order to produce a tube that is radioactive at its distal end. .

12. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Lewis et al. ('552). Klein teaches all of the limitations of the claims except that the tube segment includes a non-radioactive material into which is absorbed radioactive material. Lewis et al. teach that it is known in the art to make intra-luminal radiation devices of a non-radioactive material into which is absorbed radioactive material. It would have been an obvious engineering design choice to one skilled in the art at the time the invention was made to make a radioactive tubular segment similar that of Klein by absorbing radioactive material into a non-radioactive material in view of the teachings of Lewis et al. in order to produce a tube that is radioactive at its distal end.

13. Claims 6, 12, 13, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('284) in view of Fischell et al. ('282). Klein teaches all of the limitations of the claims except that the tube segment is adhesively attached to the balloon and that the balloon is inflated with a gas. Fischell et al. teach a catheter having an expandable radioactive source. The

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catheter includes a balloon **14** with an expandable, elastic radioactive tube segment **16** adhesively attached to the balloon **14** by an outer balloon **15** which is heat sealed (shrunk) to the inner balloon (col. 5, lines 2-6). The balloon **14** is inflated with a carbon dioxide gas to bring the tube segment into proximity to a luminal structure (col. 6, lines 51-53). It would have been obvious to one having ordinary skill in the art that since the radioactive source **16** is expandable and elastic, the dosage per surface area of the source would inherently be different in an inflated state than that of the unexpanded state. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to adhesively attach the tube segment to the balloon of a radiation treatment device similar to that of Klein in view of the teachings of Fischell et al. in order to ensure proper positioning of the expandable radioactive tube segment with respect to the balloon. It further would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a carbon dioxide gas as an inflation medium in view of the teachings of Fischell et al. in order to inflate the balloon catheter of a device similar to that of Klein as an obvious engineering design choice, merely substituting one known inflation medium for another that is capable of performing the same function.

14. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delfino et al. ('658) in view of Hess ('466). Delfino et al., as discussed hereinabove, teach all of the limitations of the claims except that the apparatus further includes a balloon catheter. Hess ('466) teaches an apparatus for restenosis treatment including a balloon catheter having a shaft **72** and an inflatable balloon **78** and a stent **74**. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a balloon catheter with

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a tubular stent similar to that of Delfino et al. in view of the teachings of Hess in order to deliver the stent to an area within an artery or vein for treatment.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-4, 6-13 and 22-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,200,256 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of the patent.

Regarding independent claims 1 and 8 of the instant application, all of the elements of the claims are recited in claims 11 and 19 of the patent. All of the aforementioned claims recite a tube segment including a radioactive material that is carried by a balloon catheter including an inflatable balloon, where the tube segment is disposed over the balloon and is made of an expandable and collapsible material such that the shape of the tube segment is determined by the

shape of the balloon. Claim 11 of the patent does not expressly state that the tube segment is longitudinally slid over the balloon. The method of using the apparatus, recited in claim 19 of the patent, indicates that the balloon catheter is inserted into a body lumen and a tube is inserted into the body lumen such that the tube segment is located over the balloon in two separate steps. It would have been obvious to one having ordinary skill in the art at the time the instant invention was made that the tube segment of the patent would have to be longitudinally slid over the balloon catheter in order to position the tube segment over the balloon after inserting the balloon catheter and the tube into a body lumen in separate steps as required by the method of claim 19 of the patent.

Claims 2 and 9 of the instant application correspond to claim 8 of the patent. Claims 3 and 10 of the instant application correspond to claim 9 of the patent. Claims 4 and 11 of the instant application correspond to claim 10 of the patent. Claim 12 of the instant application corresponds to claim 13 of the patent. Claim 6 of the instant application corresponds to claim 12 of the patent. Claim 7 of the instant application corresponds to claim 14 of the patent. Claim 13 of the instant application corresponds to claim 6 of the patent.

Regarding independent claim 22 of the instant application, all of the elements of the claim are recited in claims 19 and 22 of the patent. All of the aforementioned claims recite a method for treating a disease process in the vicinity of a luminal structure having similar method steps. Claim 22 of the patent differs from the claim of the instant application in that only a portion of the tube segment is provided with radioactive material.

Claim 23 of the instant application corresponds to claim 20 of the patent. Claim 24 of the instant application corresponds to claim 21 of the patent.

Regarding claims 25-30 of the instant application, all of the elements of the claims are recited in claim 1 of the patent. All of the aforementioned claims recite a tube segment that is carried by a balloon catheter having a shaft and an inflatable balloon, where the tube segment includes a radioactive material for administering a radiation dose which varies along a dimension of the tube segment. Claim 1 of the patent limits the dimension to an axial or longitudinal dimension as the tube of that claim is only radioactive at a distal end thereof.

Since the more specific patented claims "anticipate" the broader claims of the instant application, the claims are not patentably distinct.

Response to Arguments

17. Applicant's arguments with respect to the rejections of claims 1-4, 6-13 and 22-30 under 35 USC 102 and 103 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that the Fischell et al. ('282) patent does not teach or suggest that a radioactive tube segment could be slid, longitudinally or otherwise, over the balloon. Applicant further contends that the Columbo et al. patent does not teach or suggest a tube segment that has varying concentrations of radioactive material for producing a radiation dose that varies along the tube segment. These arguments are moot in view of the new grounds of rejection set forth hereinabove citing Klein ('284) and Delfino et al. ('658). Klein teaches a radioactive tube segment having varying concentrations of radioactive material that is longitudinally slid over a balloon catheter. Delfino et al. teach a tubular stent that has varying concentrations of radioactive material for producing a radiation dose that varies along the tube.

Applicant's arguments filed October 16, 2002 regarding the obviousness-type double patenting rejections have been fully considered but they are not persuasive.

Applicant contends that independent claims 1, 8 and 22 recite that the tube segment is slideable over the balloon, which feature is allegedly not in any of the patent claims. This argument is not persuasive. Method claims 19 and 22 of the patent both recite methods for using the apparatus of the patent where said methods recite that the balloon catheter is inserted into a body lumen and a tube is inserted such that a tube segment is located over the balloon in two separate and distinct steps. It would have been obvious to one having ordinary skill in the art that the tube segment would inherently have to be longitudinally slideable over the balloon catheter in order to insert a tube so that the tube segment is located over a balloon that has previously been inserted in the body lumen. Therefore, the obvious-type double patenting rejections of claims 1-4, 6-13 and 22-24 are maintained.

Applicant contends that independent claims 25 and 28 recite a varying radioactivity feature which is allegedly not in any of the patent claims. This argument is not persuasive. The claims of the patent recite that the tube segment is only radioactive at its distal end. Therefore, the tube has varying concentrations of radioactive material along its length. As such, the obvious-type double patenting rejections of claims 25-30 are maintained.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Charles A. Marmor, II
Examiner
Art Unit 3736

CAM
December 30, 2002